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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/509,570	09/29/2004	Jamea R. Trinkle	CGL01/0044US1	8359
38550	7590	03/17/2008		
CARGILL, INCORPORATED LAW/24 15407 MCGINTY ROAD WEST WAYZATA, MN 55391			EXAMINER	
			BLAND, LAYLA D	
			ART UNIT	PAPER NUMBER
			1623	
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			03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,570	Applicant(s) TRINKLE ET AL.
	Examiner LAYLA BLAND	Art Unit 1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 January 2008.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-7 and 11-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-166/08)
 Paper No(s)/Mail Date 1/31/2008
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's amendment filed on January 31, 2008, wherein claims 11, 12, and 18 are amended and new claims 19 and 20 are added, has been entered. Claims 1-7 and 11-20 are currently pending and are examined on the merits herein.

In view of Applicant's amendment and remarks submitted January 31, 2008, the rejection of claims 11 and 12 under 35 USC 112, second paragraph, for being indefinite with regard to the amount of caustic used, is withdrawn.

Applicant's declaration James Trinkle submitted January 31, 2008 under 37 CFR 1.132, is acknowledged and will be further discussed below.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

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skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation “wherein the chitosan produced has an average molecular weight of greater than 80,000” lacks of adequate written description since these recitations read literally on any molecular weight greater than 80,000, without upper limit.

The specification as originally filed does not provide support for greater than 80,000 without upper limit. See *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), regarding a corresponding new claim limitation with no upper limit. See also *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000). Consequently, there is nothing within the instant specification which would lead the artisan in the field to believe that Applicant was in possession of the invention as it is now claimed. See *Vas-Cath Inc. v. Mahurkar*, 19 USPQ 2d 1111, CAFC 1991, see also *In re Winkhaus*, 188 USPQ 129, CCPA 1975.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (*Journal of Food Biochemistry* 23 (1999) 187-196, of record) in view of

Butelman et al. (EP 0400346A2, May 12, 1990, of record) and Konda et al. (Biol. Pharm. Bull. 23(12) 1458-1464 (2000), of record).

Hu et al. teach a two-step extraction method for fungal chitosan which provides chitosan essentially free of impurities [see abstract]. Fungal mycelia were autoclaved (about 15 psig) in a 1M-50% caustic soda solutions at 121° C for 15-60 minutes [Table 1]. The alkali-insoluble materials obtained were then further autoclaved in aqueous acetic acid solution [abstract]. After extraction, the chitosan was washed and centrifuged, freeze-dried and weighed [page 190, Chitosan Extraction]. Concentrated alkali (50%) produced the highest yield of chitosan [page 191, Table 1]. The longest extraction (60 min) produced chitosan with the lowest molecular weight [page 192, lines 16-18].

Hu et al. do not teach reaction times longer than 1 hour, pressure higher than 15 psig, or temperature higher than 121°C.

Butelman et al. teach the extraction of chitosan from arthropod waste material with saturated steam under pressure in the presence of an alkaline agent [abstract]. A mixture of shells derived from crustaceans and caustic soda solution is treated with saturated steam at a temperature of between 150 and 300° C and a pressure between 15 and 30 bar (about 217-435 psig) for 2-15 minutes [column 2, lines 31-42]. The method produces complete disgregation of the starting material [column 2, lines 45-50]. The chitosan product has molecular weight of 20,000-100,000 and deacetylation greater than 95% [column 3, lines 12-18].

Konda et al. teach that administration of low molecular weight chitosan prevents the progression of non-insulin-dependent diabetes in mice [page 1464, last paragraph].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to produce chitosan by reacting fungal biomass with sodium hydroxide, at elevated temperature and pressure, for long periods of time. The use of elevated temperatures and pressures and varied concentrations of caustic is already known in the art, as taught by Hu et al. and Butelman et al. The skilled artisan would have been motivated to employ long reaction times in order to produce lower molecular weight chitosan, as taught by Hu et al., because low molecular weight chitosan has desirable properties, as taught by Konda et al. One of ordinary skill in the art would understand that temperature, pressure, reaction time, and concentration are all parameters that are easily manipulated to drive reactions forward. Thus, the skilled artisan, using the above references for guidance, could optimize these parameters to achieve chitosan having the desired molecular weight and degree of deacetylation.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one

of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments and the declaration of James Trinkle submitted January 31, 2008 have been considered but are not persuasive.

Applicant argues that the claimed method produces chitosan of high molecular weight, as discussed in the declaration of James Trinkle, and that one of ordinary skill in the art would not have known to increase the duration of the reaction to produce high molecular weight chitosan. None of claims 1-7 or 11-18 contain limitations regarding molecular weight of the chitosan produced. Thus, the claims are still obvious for the reasons stated in the above rejection.

Applicant argues that the Butelman reference is drawn to the extraction of chitosan from shellfish waste, which does not contain glucans, and thus one of ordinary skill in the art would not be motivated to combine this teaching with the teaching of Hu. The Butelman reference is used in combination with Hu to further illustrate that high temperature and pressure are known in the art for the production of chitosan. Although Butelman is drawn to extraction from chitosan from shellfish, the process is similar to that taught by Hu (caustic, high temperature, high pressure). The skilled artisan, using the guidance provided by Hu, could easily conceive of increasing temperature and pressure for the extraction of chitosan from fungal biomass. Butelman provides the skilled artisan with more guidance and a greater expectation of success regarding modification of Hu's procedure. Thus, Butelman is relevant.

Applicant argues that Konda does not provide motivation or teachings that would lead one of ordinary skill in the art to combine the cited references. The teachings of Hu imply that a long reaction time at high temperature and pressure results in chitosan of lower molecular weight than does reaction for a shorter time. Konda teaches the desirability of low molecular weight chitosan. Thus the skilled artisan would be motivated to extend the reaction times of Hu in order to obtain desirable low molecular weight chitosan.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (*Journal of Food Biochemistry* 23 (1999) 187-196, of record) in view of Butelman et al. (EP 0400346A2, May 12, 1990, of record) and Konda et al. (*Biol. Pharm. Bull.* 23(12) 1458-1464 (2000), of record), as applied to claims 1-7 and 11-18 above, and further in view of Fan et al. (WO0168714, September 20, 2001).

Hu et al., Butelman et al., and Konda et al. teach as set forth above.

Hu et al., Butelman et al., and Konda et al. do not teach production of chitosan from *Aspergillus* biomass.

Fan et al. teach production of chitosan from *Aspergillus niger* by extraction in caustic solution at temperatures greater than 95°C for at least 10 hours [see abstract and pages 7 and 8, Example].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare chitosan from *Aspergillus* biomass using a procedure modified from the teachings of Hu et al. Hu et al. teach production of chitosan from

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fungal biomass but do not teach the use of *Aspergillus* biomass in particular. Fan et al. teach that chitosan can be produced from *Aspergillus* biomass using caustic at high temperature. Thus, the skilled artisan could have substituted *Aspergillus* biomass in the procedure of Hu et al. with predictable results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623

/Shaojia Anna Jiang, Ph.D./
Supervisory Patent Examiner, Art Unit 1623